PERCUTANEOUS GASTROINTESTINAL ANCHORING KIT

BACKGROUND OF THE INVENTION

[0001] The present invention relates to pre-packaged surgical kits in general, and more particularly to surgical kits for percutaneous gastrointestinal anchoring procedures or a gastropexy kit.

[0002] Various medical procedures are simplified by providing the physician with a kit that contains the majority, if not all, of the necessary medical articles that the physician will need to complete a particular procedure. Kits may include articles such as, for example, drapes, syringes, scalpels, needles, clamps, gauze, sponges, drugs, sutures, and devices. Such kits are commonly provided for procedures such as, for example, percutaneous endoscopic gastrostomy ("PEG") and laparoscopic jejunostomy. These kits reduce the time spent by hospital personnel gathering the appropriate articles that are required for a particular procedure and ensure that the surgeon has each article at hand at the appropriate point in the procedure.

[0003] A PEG procedure is utilized to place a feeding tube into a patient that extends from the interior of the patient's stomach exteriorly of the patient. The feeding tube permits nutrients to be placed directly into a patient's stomach. This may be necessary when a patient has a disorder of the gastrointestinal tract, malabsorption (impaired absorption of nutrients, vitamins or minerals from the diet by the lining of the small intestine), or neurological or renal disorders. The feeding tube inserted using a PEG procedure is kept in place until a stoma is formed. Once a stoma is formed, the PEG feeding tube may be removed and replaced with an alternate feeding device.

[0004] Prior to placement of any feeding tube, it has been found that it is particularly desirable to anchor the anterior wall of the stomach to the abdominal wall as a step prior to creating the stoma tract through the two. Thus attachment has been found to be critical as it helps to prevent inadvertent separation and exposure of the peritoneal cavity to contamination and possible peritonitis.

[0005] Typically a T-shaped fastener or anchor is percutaneously introduced into the gastric lumen or stomach. This fastener consists of wire or other filament affixed to a small metal bar or rod. The point at which the two are conjoined is at the center of the bar. The overall visual look of the device is that of the letter "T", with the wire forming the vertical component and the bar forming the horizontal or cross component. The device is typically loaded into an introducer needle or the like with the rod pivoted at the connection with the wire so that the two are essentially in alignment. The introducer is inserted into the stomach, the wire pushed distally from the introducer until the horizontal bar is deployed at which time it at least partially pivots into the T-configuration. The introducer is retracted from the stomach and a tractive force is applied to the wire, the T-component seats against the wall of the stomach and continued pulling serves to draw the anterior wall of the stomach to the abdominal wall.

[0006] Although these devices perform the function that they are designed for, a number of problems do exist with them. Typically the T-shaped fastener or horizontal T-bar is not removable back through the incision. As such once the procedure has been completed and the device ready to be removed, the wire is typically cut and the T-bar is left in the body cavity where it is allowed to pass naturally in the patient's stool. In many cases the T-bar is not passed and remains within the body cavity. Consequently, in many cases these initial placement devices are often not readily removable without additional invasive surgical procedures. This is further complicated by the fact that during the six to eight weeks it takes for the fistula's stoma tract to be established, the anchoring mechanism i.e., the small metal T-shaped fastener may embed itself into the gastric or intestinal wall and ultimately lead to infection. Furthermore, the edges of the T-bar often irritate the stomach lining which can be uncomfortable for the patient. Although these devices are often formed of stainless steel, hydrochloric acid contained within the gastric juices of the patient may cause some minor erosion to the device due to the time in which the device is maintained in place.

[0007] As described above, in order to achieve the desired seal between the stomach and the abdominal wall, a tractive force must be applied to the anchoring mechanism. This force is applied in such a way so as to pull the stomach cavity to the abdominal wall in order to induce the penetration through the tissue layers to fuse or heal together thus creating the passage or stoma leading from the patient's stomach to an external environment. Accordingly, it is necessary to apply this tractive force for a period of a couple of days through a couple of weeks until the stoma site adequately heals. During this period the patient has reduced mobility which may lead to additional post-operative complications.

[0008] While gastropexy devices do exist, there is a need and desire for a gastropexy kit which provides all of the components necessary to enable percutaneous gastrointestinal anchoring prior to the placement of a feeding tube in the patient. Such a kit would prove useful in fostering the permanent fusion of the stomach wall to the abdomen. A less traumatic anchoring system provided in such a kit could serve to reduce the invasiveness of the procedure, to greatly enhance wound healing, to enable immediate, post-placement gastric access for feeding and drainage, and ultimately to allow for the atraumatic removal of the anchoring system. As such what is needed is a kit containing an anchoring or fixation device that is easy to place within an internal body cavity, allows for the formation of a stoma between the internal body cavity and the external environment without significantly impacting the patient's mobility, and enables the clinician to easily remove the fixation device when it is no longer necessary.

SUMMARY OF THE INVENTION

[0009] In response to the foregoing problems and difficulties encountered by those of skill in the art, the present invention is directed toward a percutaneous gastrointestinal anchoring kit having an anchor, an introducer, a guide, an inflator, and a retainer. The anchor contains a ballooned region at a distal end of the anchor and a shaft portion extending from the ballooned region to a proximal end of the anchor. The introducer traverses the body tissue layers from an exterior surface of a patient body to the stomach and inserts the anchor within the stomach. The guide positions the ballooned region of the anchor from the bore into the gastric lumen while enabling the proximal end of the anchor to be manipulable at an exterior surface of the patient body. The inflator is used to introduce a fluid into or remove a fluid from the anchor so as to selectively inflate or deflate the ballooned region within the gastric lumen. The retainer secures the anchor within the gastric lumen when the ballooned region is inflated by seating against the exterior surface of the patient body and placing a tractive force on the ballooned region so as to pull the gastric lumen to an interior abdominal wall of the patient body.

[0010] In another embodiment, the invention is directed toward an apparatus for insertion into a body orifice for